Elegra Millennium Enhanced Diagnostic Ultrasound System 510(k) Submission

AUG 1 2000

510(K) SUMMARY

Elegra Millennium Enhanced Diagnostic Ultrasound system

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. Submitted By:

Siemens Medical Systems, Inc., Ultrasound Group 22010 S.E. 51st Street Issaguah, WA 98027-7002

Contact Person:

Judi Hoffman Regulatory Affairs

Phone: (425) 557-1229 FAX: (425) 391-9198

Date Prepared:

April 30, 2000

2. Proprietary Name:

Elegra Millennium Enhanced Ultrasound System

Common/ Usual Name:

Diagnostic Ultrasound System with Accessories

Classification Name:

21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

FR # 892.1550
FR # 892.1560
Product Code 90-IYO
Product Code 90-IYO
Product Code 90-IXO

3. Predicate Device:

K945072, 11/21/95, cleared as the Q4000, marketed as the Elegra Advanced with subsequent modifications.

K945773, 8/7/95, cleared as Versa, marketed as SONOLINE Versa Pro and SONOLINE Sienna with subsequent modifications.

4. Device Description:

The Elegra Millennium Enhanced is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in: B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, or 3D imaging, on a CRT display.

The Elegra Millennium Enhanced, has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

Elegra Millennium Enhanced Diagnostic Ultrasound System 510(k) Submission

- AIUM/NEMA, 1992, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1992 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN 60601-1
 - EN 60601-1-1
 - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The Elegra Millennium Enhanced ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

Elegra Millennium Enhanced is substantially equivalent to the SONOLINE® Elegra, cleared via K945072, and modified via K950157, K961833, K981626, K980557 and K981528; and some features of the SONOLINE® Versa, cleared via K945773, and modified via K962142, K962882, and K992046. All systems transmit ultrasonic energy into patients, then perform postprocessing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

AUG 1 2000

Judi Hoffman Senior Regulatory Affairs Specialist Siemens Medical Systems, Inc 22010 S.E. 51st Street Issaquah, WA 98029-7002

Re:

K001400

Elegra Millenium Enhanced Diagnostic Ultrasound System

Regulatory Class: II

21 CFR 892.1550/Procode: 90 IYN 21 CFR 892.1560/Procode: 90 IYO 21 CFR 892.1570/Procode: 90 ITX

Dated: April 30, 2000 Received: May 3, 2000

Dear Ms. Hoffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Elegra Millenium Enhanced Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2 Probe
P3-2 Phased Array Transducer
C5-2 Curved Array transducer
CX5-2 Curved Array Transducer
C7-3 Curved Array Transducer
VF7-3 Linear Array Transducer
EC9-4 Curved Array Transducer
VFX9-4 Linear Array Transducer
VF10-5 Linear Array Transducer
P9-4 Phased Array Transducer
VF13-5 Linear Array Transducer
VFX13-5 Multi-D Array Transducer
PX5-2 Phased Array Transducer
M7-4 Multiplane TEE Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Director, Division of Reproductive, Abdominal, and Radiological Devices Office of Device Evaluation

Center for Devices and

Radiological Health

510 (k) Number (if known):

Device Name: Intended Use:

Elegra Millennium Enhanced Diagnostic Ultrasound System

Ultrasound imaging or fluid flow analysis of the human body as follows:

		- 18 34.				Mo	ode of Opera	ation			
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		Р	Р	P	P	P	Р		BMDC (P)	Р	P
Abdominal		Р	Р	Р	Р	Р	P		BMDC (P)	Р	P
Intraoperative Abdominal					Р						
Intraoperative Neurological									51150 (B)		-
Pediatric		Р	P	P	P	Р	Р		BMDC (₽)	"P. "	Р
Small Organ (Specify) **		Р	Р	Р	Р	Р	Р		BMDC (P)		Р
Neonatal Cephalic		P	Р	Р	Р	Р	Р		BMDC (P)	P	Р
Adult Cephalic		Р	Р	Р	Р	Р	P		BMDC (P)		Р
Cardiac		Р	Р	Р	Р	Р	Р		BMDC (P)		Р
Trans-esophageal		Р	P	Р	Р	Р	Р		BMDC (P)		N
Transrectal		Р	Р	Р	Р	Р	Р		BMDC (P)		Р
Transvaginal		Р	Р	P	Р	Р	Р		BMDC (P)	N	Р
Transurethral											
Intravascular									NU - NECTABLE	al Constanting States and Constanting	1.000
Peripheral vessel		Р	Р	Р	P	P	Р	<u> </u>	BMDC (P)	Р	Р
Laparoscopic									1 2 2 32,	1, 1,474.50	
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		BMDC (P)	Р	Р
Musculo-skeletal Superficial		Р	Р	Р	Р	Р	Р		BMDC (P)	N	N
Other (specify)						<u> </u>				<u></u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K00 1400

Ultrasound Group

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: Intended Use: CW 2 Probe for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	lode of Opera	ation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal					P						
Abdominal	İ				P						
Intraoperative Abdominal					P						الدينين والمحاد
Intraoperative Neurological										⊃ ¢	
Pediatric					P						
Small Organ (Specify) **					P				adding the groups of the	i wys y wy	a fart fugger o
Neonatal Cephalic					P						
Adult Cephalic					P	-				, ,	
Cardiac					P						
Trans-esophageal	1		1						The second of the second	Sala - Marin Marin Marin Marin	- Grys (p
Transrectal			************								
Transvaginal											
Transurethral			1								
Intravascular	İ										
Peripheral vessel					P				i takifi i ati g	Control de Novembro de 18	. 1944-00
Laparoscopic		<u> </u>	ļ .								
Musculo-skeletal Conventional					P				e e yester e e	and the second second	
Musculo-skeletal Superficial										. 120111.00.00	
Other (specify)											

N = new indication; P = previously	cleared by FDA; $E = add$	ed under Appendix E			
Additional Comments:					
** small organs (breast, testes, thyro	oid, penis, prostate)				
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. Co	ncurrence of CDRH, Office	ce of Device Evaluatio	n (ODE)		

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K001400</u>

510 (k) Number (if known):

Device Name:

P3-2 Phased Array Transducer for use with Elegra Millennium Enhanced

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N	N	N .	N		BMDC (N)	N	N
Abdominal		Ν	Ν	N	Ν	N	N		BMDC (N)	N	N
Intraoperative Abdominal											i de la constanta
Intraoperative Neurological								-			
Pediatric		N	Ν	N	N	N	N		BMDC (N)	N .99.4	
Small Organ (Specify) **									≪ .	7 14-23-4	1.500
Neonatal Cephalic		N	N	N	Ν	N	N		BMDC (N)	N	N
Adult Cephalic		N	Z	И	N	Ν.	N		BMDC (N)	N	N.
Cardiac		Ν	Z	Ν	N	N	N		BMDC (N)	N	N
Trans-esophageal											
Transrectal									and the Grace Control	mut to entra a la mage	. 1.147,0,1,19
Transvaginal									· 100 - 1		
Transurethral									27,250.00	. Projekty kaj	a de la companya de l
Intravascular						-			15.41		
Peripheral vessel		N	N	N	N	N	N		BMDC (N)	N	N
Laparoscopic									7 Typewell told	A459505 1298	1 salaha di sa
Musculo-skeletal Conventional									24 4 2 2 2 2 2	*	
Musculo-skeletal Superficial										s (·
Other (specify)									a great plane and	a state to assist	i sager i

Other (specify)									a special process	a company	i sager
N = new indication; P	= prev	iously	clear	ed by F	DA; E	= added und	der Append	ix E			
Additional Comments:											
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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number 500 1400

510 (k) Number (if known):

Device Name: Intended Use:

PX5-2 Phased Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						М	ode of Opera	ation			
Clinical Application	Α	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	Z	N	N	N	N		BMDC (N)	N	2
Abdominal		Ν	Z	N	N	N	N		BMDC (N)	N	N
Intraoperative Abdominal											and the second
Intraoperative Neurological									,		
Pediatric		N	N	N	N	N	N		BMDC (N)	N A	N
Small Organ (Specify) **									7	egree bakeen og overlæg	فيحن والارافاقي وفاحون اد
Neonatal Cephalic		Z	Z	N	N	N.	N		BMDC (N)	N	N
Adult Cephalic		N	Ν	N	N	N	N		BMDC (N)	N	N
Cardiac		Ν	N	N	N	N	N		BMDC (N)	N	N
Trans-esophageal											
Transrectal									e e e e e e e e e e e e e e e e e e e	was a comment	garden ar ese
Transvaginal										and the same	
Transurethral						·			Comments of Comments	100 - 110 - 110 - 110 - 110	an contract of the
Intravascular											5 5 .
Peripheral vessel		N	N	N	N	N	N		BMDC (N)	N	N
Laparoscopic											1.00
Musculo-skeletal Conventional									en en objektiv skienskip	et i e consul	et someone egget over
Musculo-skeletal Superficial											
Other (specify)									in the second	rus atrium en en en en	. S. av. Jr. 1921 90

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Additional Co	omments:				
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rescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number.

510 (k) Number (if known):

Device Name: Intended Use:

C5-2 Curved Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation												
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging			
Ophthalmic														
Fetal		N	N	N		N	N		BMDC (N)	N	N			
Abdominal .		N	N	N		N	N		BMDC (N)	N	N			
Intraoperative Abdominal											1			
Intraoperative Neurological														
Pediatric		N	N	N		N	N		BMDC (N)	N	N			
Small Organ (Specify) **									A ⁵⁰⁹ , 80	ari erak	n in in national meeting			
Neonatal Cephalic				<u> </u>										
Adult Cephalic									4.4%	erite engaga MA	an grande and a			
Cardiac					_									
Trans-esophageal							_							
Transrectal									100 Mg/s	1975 - 11. H. (1 778)	the second second			
Transvaginal										. 4				
Transurethral									11000	rija kar sasah	enderen bei 🔾 💮 en			
Intravascular														
Peripheral vessel		N	Ν	Z		N	N		BMDC (N)	Ν	N			
Laparoscopic														
Musculo-skeletal Conventional		Ν	N	N		N	. N		BMDC (N)	N 	N			
Musculo-skeletal Superficial														
Other (specify)									1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Jimovidi	and the second			

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>KOOI 400</u>

510 (k) Number (if known):

Device Name: Intended Use:

CX5-2 Curved Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Ī	Mode of Operation										
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging	
Ophthalmic												
Fetal		Ε	Ε	E		E	E		BMDC (E)	E	E	
Abdominal		Ε	Ε	E		E	E		BMDC (E)	E	E	
Intraoperative Abdominal Intraoperative										. СУДА	ুকো বিভাগ	
Neurological		E	E	E		E	E		BMDC (E)	Е	E	
Pediatric Small Organ (Specify) **			E			L	_	·	DIVIDO (L)		in alternativada	
Neonatal Cephalic												
Adult Cephalic										and the state of t	11	
Cardiac											116.0	
Trans-esophageal												
Transrectal									. \$20.74 _{0.00} (8)	THE TOP SHIP CHARACTER	. 4. 1911.855.00	
Transvaginal												
Transurethral									1 7 2 COVE	. com totalegas	.00	
Intravascular									<u>ļ</u>			
Peripheral vessel		E	E	E		E	E		BMDC (E)	E	E	
Laparoscopic			<u> </u>	1	:							
Musculo-skeletal Conventional		Е	E	E.		E	Е		BMDC (E)	E	Е	
Musculo-skeletal Superficial												
Other (specify)					. 500				The second section of the second seco	1 11 11 11 11 11 11 11		

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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Olvision Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

519(k) Number < 00/400

510 (k) Number (if known):

Device Name: Intended Use:

P9-4 Phased Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal		N	N	N	N	N	N		BMDC (N)	N	N
Intraoperative Abdominal Intraoperative										***************************************	
Neurological											
Pediatric		N	N	N	N	N	N		BMDC (N)	N	N
Small Organ (Specify) **									10		17 mm, 12 de
Neonatal Cephalic		N	N	N	N	N	N		BMDC (N)	N	N .
Adult Cephalic										and the second of the second	3.00
Cardiac		N	N	N	N	N	N		BMDC (N)	N .	N.
Trans-esophageal											
Transrectal									er especialista.	Now you all in Stonewick	1, 34, 19
Transvaginal											
Transurethral									ur a Pritograph	Line to the transfer of	41.752
Intravascular											
Peripheral vessel		N	N	N	N	N	N		BMDC (N)	N	N
Laparoscopic							<u> </u>				
Musculo-skeletal Conventional		N	N	N	N	N	N		BMDC (N)	N	Ŋ
Musculo-skeletal Superficial										,	
Other (specify)									11 - 11 - 12 - 13 - 13 - 13 - 13 - 13 -	in a supera	Serie Head

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Additional Comments:				
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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

310(k) Number Ko 01400

510 (k) Number (if known):

Device Name: Intended Use:

C7-3 Curved Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic					***************************************						
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal										4.	1 115 (34)
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **			-						-	200 Table (2008)	8 July 16 J
Neonatal Cephalic			<u> </u>								
Adult Cephalic									11/1/1/2012/2012/2013/8	(1) A A Physical	· · · · · · · · · · · · · · · · · · ·
Cardiac											
Trans-esophageal											
Transrectal									general general system in Selfig	ry, eleven in the york, dage	100 m 113 d 1
Transvaginal									<u> </u>		
Transurethral									1752 L 6989	CONTRACTOR STATE	10 10 8 10
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial											
Other (specify)									1 100gartis 100ga	4 10 1 07 9 M. M. M. MARKEN	1982 (1982)

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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K00/400

510 (k) Number (if known):

Device Name:

EC9-4 Curved Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows: Intended Use:

						Me	ode of Opera	ation			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal		·									
Intraoperative Abdominal Intraoperative										r.c.	. John Consultation
Neurological										7. 5.14	
Pediatric											
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N 	N
Neonatal Cephalic	<u> </u>			<u> </u>							
Adult Cephalic				<u> </u>					. Jegun	and the majority and spiness	~14 <u>2,574</u> .*
Cardiac	T				<u> </u>						
Trans-esophageal											
Transrectal		N	N	N		N	N N		BMDC (N)		
Transvaginal		N	N	N		N	N		BMDC (N)	N	N ·
Transurethral					<u> </u>				. 14.54	10 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	. September 1
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional										S 2-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	
Musculo-skeletal Superficial											
Other (specify)									2495.0	1 - K. S. J. J. S. J. S.	745047234

N = new indication; P = previously cleared by FDA; E = added under Appendix E Additional Comments: ** small organs (breast, testes, thyroid, penis, prostate)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number.

510 (k) Number (if known):

Device Name: Intended Use:

M7-4 Multiplane TEE Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imagin
Ophthalmic										ĺ	
Fetal											
Abdominal											
Intraoperative Abdominal											20 5000
Intraoperative Neurological							-				
Pediatric											
Small Organ (Specify) **							·		5274	an internet a succession	, 15 17, 15 min
Neonatal Cephalic											
Adult Cephalic						*			150 000 0000	or. The second war	e latina i dia
Cardiac											
Trans-esophageal		N	N	N	N	N	N		BMDC (N)	N	N
Transrectal									2,450,600	وروفادو والا	1 1 1 1 1 1 1 1 1 1 1
Transvaginal											
Transurethral									1 500	1. 91454	1,1800,000
Intravascular											
Peripheral vessel											
Laparoscopic									2,12,244,00	Standard Comme	
Musculo-skeletal Conventional									no compa		
Musculo-skeletal Superficial									. 1		
Other (specify)			$\neg +$	-					14,075	11 11 1 12 12 12 12 12 12 12 12 12 12 12	

Supernolai	4 1	1 1					-	ı		
Other (specify)							<u> </u>	teach	1 477,7589	
N = new indication; P	= previous	ly cleared b	y FDA; E	= added (ınder Appe	ndix E				- 111 - 7 : -
Additional Comments:										
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		Pr	escription	Use (Per	21 CFR 80	1.109)				
				2						

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(Division Sign-Off)

510(k) Number.

and Radiological Devices

Division of Reproductive, Abdominal, ENT,

510 (k) Number (if known):

Device Name: Intended Use:

VF7-3 Linear Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging		
Ophthalmic													
Fetal		N	N	N		N	N		BMDC (N)	N	N		
Abdominal		N	N	N		N	N		BMDC (N)	N	N		
Intraoperative Abdominal Intraoperative	·										. When the		
Neurological	ļ		ļ	ļ					D1400 (41)	45070	The second		
Pediatric		N	N	N		N	N		BMDC (N)	N	N		
Small Organ (Specify) **		ļ. 							.3	ring ty Miles	and the same		
Neonatal Cephalic													
Adult Cephalic									0.000000	7 - 175-4 CM			
Cardiac													
Trans-esophageal			<u> </u>										
Transrectal									et alget 7 - NAGA		e englisher i		
Transvaginal													
Transurethral									2 max 1 min 1 min	100 100 100 100 100 100 100 100 100 100	1.000,0000		
Intravascular									<u> </u>				
Peripheral vessel		.N	N	N		N	N		BMDC (N)	N	N		
Laparoscopic													
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	, N	N		
Musculo-skeletal Superficial													
Other (specify)										C.V44	2.00		

N = new indication; P = previously contracts	eared by FDA; E = added	under Appendix E	· · · · · · · · · · · · · · · · · · ·	
Additional Comments:				•.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>KOO1400</u>

K001400

510 (k) Number (if known):

Device Name: Intended Use: VF10-5 Linear Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Me	ode of Opera	ation			
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic	1										
Fetal		N	N	N		N	N		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	· N
Intraoperative Abdominal											
Intraoperative Neurological											·
Pediatric		N	N	N		N	N		BMDC (N)	N	N
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N	N
Neonatal Cephalic		N	N	N		N	N		BMDC (N)	N	N
Adult Cephalic					1				,		
Cardiac										19.4%	ers, row
Trans-esophageal											
Transrectal									50	and the months of the	an a tan .
Transvaginal											
Transurethral											
Intravascular										11111111111	
Peripheral vessel		N	N	N		N	N		BMDC (N)	N .	N
Laparoscopic	1								1. 1147.0	a in a management	ta transition
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	N	N
Musculo-skeletal Superficial		N	N	N		N	N		BMDC (N)	. N	N
Other (specify)									0.5 0.5 0.8	a see see see see see	

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K00 1400

K001400

510 (k) Number (if known):

Device Name: Intended Use:

VFX9-4 Linear Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Ī					M	ode of Opera	ation			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal		N	N	N		N	N.		BMDC (N)	N	N
Abdominal		N	N	N		N	N		BMDC (N)	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N		N	N		BMDC (N)	N 3	55 , a N ,
Small Organ (Specify) **		N	N	N		N	N		BMDC (N)	N	N
Neonatal Cephalic	:	N	N	N		N	N		BMDC (N)	N	N .
Adult Cephalic					•						
Cardiac									1 1 14	Line Service Control (Service)	eli, ja elikerikaja ja
Trans-esophageal											
Transrectal	1								1 (1.000)	We say a security of the	1, 17,240 (54.14)
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		BMDC (N)	N	N
Laparoscopic									er i'r drhegafyr	i gartaenn son	un grane
Musculo-skeletal Conventional		N	N	N		N	N		BMDC (N)	. N	N
Musculo-skeletal Superficial											
Other (specify)	T	1			1				en distributed with	5.44%	Anna Anna a

N = new indication; P = previous	ly cleared by FDA; E = added i	under Appendix E	
Additional Comments:			
** small organs (breast, testes, th	yroid, penis, prostate)		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K001400</u>

510 (k) Number (if known):

Device Name: Intended Use:

VF13-5 Linear Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal								,			
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological									D1100 (5)		
Pediatric		Ε	E	E	E	E	E	·	BMDC (E)	Е	E
Small Organ (Specify) **		Ε	Ε	E	E	E	E		BMDC (E)	"" E , ",	. E
Neonatal Cephalic									ļ		
Adult Cephalic									ASSESSMENT OF STREET	1975 - 1975 - 1975 - 1975	,, sep se
Cardiac									ļ		
Trans-esophageal									1.000,000,000	and the state of the state	
Transrectal									2. 30 3, 7 7 8, 300	a i i i i i i i i i i i i i i i i i i i	t to stwo t
Transvaginal											
Transurethral									1 1 10 10 10 10 10 10 10 10 10 10 10 10	- the same and the	
Intravascular											
Peripheral vessel		Ε	E	E	E	E	E		BMDC (E)	Ε	E
Laparoscopic										ļ	
Musculo-skeletal Conventional		E	E	E	Ε	E	E		BMDC (E)	E,	E
Musculo-skeletal Superficial		Ε	Е	E	E	E	E		BMDC (E)	E	E
Other (specify)									t garanta	of an any seed of	

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Additional Comments:

** small organs (breast, testes, thyroid, penis, prostate)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K001400

510 (k) Number (if known):

Device Name: Intended Use:

VFX13-5 Multi-D Array Transducer for use with Elegra Millennium Enhanced

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation		· · · · · · · · · · · · · · · · · · ·	
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	3-D Imaging
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		E	ш	Е	Е	E	Е		BMDC (E)	E	Е
Small Organ (Specify) **		E	Е	Е	E	Е	E		BMDC (E)	E	E
Neonatal Cephalic											
Adult Cephalic						-			12 (27 18 p. gr.)	9 922 1 get	
Cardiac											
Trans-esophageal											
Transrectal								,	Complex and the property of th	e la ser de la co	2 3.5.5
Transvaginal											
Transurethral									. 15 6545 - 14	sa sa pinana ana ara	d of same
Intravascular											
Peripheral vessel		Ε	E	E	E	E	Е		BMDC (E)	E	E
Laparoscopic											
Musculo-skeletal Conventional		Е	Ε	E	E	Ε	E		BMDC (E)	E	Е
Musculo-skeletal Superficial		Е	E	· E	E	Е	E.		BMDC (E)	E	E
Other (specify)									11 x 11 11 11 11 11 11 11 11 11 11 11 11	\$20.000.000	

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Additional Comments:

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